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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/089,871	06/04/1998	RUDOLF CAROLUS MARIA BARENDSE	97253-A	3289

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EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/089,871

Applicant(s)

BARENDSE ET AL.

Examiner

Delia M. Ramirez

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-28,31-35,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-28,31-35,39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 29.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1652

DETAILED ACTION

Status of the Application

Claims 18-28, 31-35, 39-40 are pending.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/13/2002 has been entered.

Applicant's amendment of claims 18-19, 31, 34 and 40 in Paper No. 28, filed on 12/13/2002 is acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Priority

1. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to provisional application No. 60/048,611 filed on 06/04/1997.
2. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. 119(a)-(d) to EPO 97201641.4 filed on 06/04/1997.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 1/13/2003 was filed after the request for continued examination under 37 CFR 1.114. The submission is in compliance with

the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner

Claim Rejections - 35 USC § 112, Second Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 18-28, 31-32, 34-35, 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 18 and 19 (claims 20-28, 31-32, 34-35, 39-40 dependent thereon) are indefinite in the recitation of “non-fibrous solid carrier comprising at least 15% (w/w) of an edible carbohydrate polymer” for the following reasons. It is unclear what the meaning of the term is within the context of the claim and the specification provides no definition of the term. The specification’s only reference to the term is that a suitable carrier is non-fibrous for easier granulation (page 6, lines 19-20). Since the specification fails to disclose examples of non-fibrous carriers, one cannot determine if the term “non-fibrous carriers” refers to edible digestible non-fibrous carriers or non-digestible non-fibrous carriers. It is noted that the specification states that at least 15% of the solid carrier can comprise an edible carbohydrate polymer such as starch (page 7, lines 15-24). Since starch can be a non-fibrous solid carrier as well as an edible carbohydrate polymer, the term “non-fibrous solid carrier comprising at least 15% (w/w) of an edible carbohydrate polymer” is equivalent to “starch comprising at least 15%

Art Unit: 1652

of starch". For examination purposes, the term "non-fibrous solid carrier" will be interpreted as "solid carrier". Correction is required.

7. Claim 31 (claims 34 and 35 dependent thereon) is indefinite in the recitation of "both a granulate according to (a) and a phytase-containing granulate according to (b)" for the following reasons. The term is redundant since the granulate of claim 18 is a phytase-containing granulate having at least 6000 FTU/g of activity. For examination purposes, claim 31 will be interpreted as being directed to a composition comprising either the granulate of claim 18 or a phytase-containing granulate having at least 6000 FTU/g of activity. Correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Nielsen et al. (WO 95/28850, November 2, 1995; cited in previous Office Actions). Nielsen et al. teaches an *Aspergillus* phytase-containing granulate comprising 10,000 FTU/gram of total composition which is an animal feed additive (page 5, lines 25-29; page 10, lines 16-21; page 11, lines 27-30; page 12, lines 18-21).

Claims 31-33 are directed to a composition comprising a phytase-containing granulate with an activity of at least 6000 FTU/gram wherein the composition is edible and can be used in animal feed. Therefore, the teachings of Nielsen et al. anticipate the claims as written.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 18-21, 24-28, and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995; cited in previous Office Actions) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996).

Nielsen et al. teaches an *Aspergillus* phytase-containing granulate comprising 10,000 FTU/gram of total composition (page 5, lines 25-29; page 10, lines 16-21; page 11, lines 27-30; page 12, lines 18-21). Nielsen et al. teaches that the phytase is derived from several strains of *Aspergillus* such as *niger* and *ficum* (page 7, lines 4-6). Furthermore, Nielsen et al. teaches a phytase-containing feed additive comprising additional glucosidase enzymes such as xylan-endo-1,3- β -xylosidase and endo-1,6- β -glucanase (page 11, lines 5-19). Nielsen et al. teaches that the

Art Unit: 1652

phytase granulate can be used as an additive for animal feed (page 10, lines 16-21). Nielsen et al. does not teach a phytase-containing granulate comprising an edible carbohydrate polymer, starch or a gel-forming compound.

Ghani teaches an enzyme granulate and compositions thereof, wherein a solid carrier can be a starch-containing compound such as soy flour, soy grits, corn flour, ground corn cobs, etc. (column 2, lines 25-34). In one of the examples provided by Ghani, the carrier contains 90% (w/w) of soy flour (column 6, lines 43-48; 10 g corn syrup solids per 100 g soy flour). Ghani also teaches enzyme granulates which comprise hydrolyzed starches and gums (column 2, lines 35-52) as well as low viscosity alginates and algin blends (column 2, lines 53-57; gel forming compounds). Furthermore, the enzyme granules of Ghani contain divalent cations such as those in ammonium sulfate (column 3, lines 14-25). In addition, Ghani teaches that the amount of enzyme to be used in a granule can be adjusted according to the activity desired for the finished product (column 3, lines 45-47). Ghani does not teach an enzyme granulate where the enzyme is a phytase.

Claims 18-19 are drawn to a phytase granulate having at least 6000 FTU per gram where the granules are prepared using a solid carrier which comprises at least 15% (w/w) of an edible carbohydrate polymer and the phytase is obtained from a solution having a concentration of at least 14000 FTU per gram of solution. Claim 20 adds the limitation that the granulate should contain at least one divalent cation and claim 21 adds the limitation that the granulate should contain a gel-forming compound. Claim 24 adds the limitation that the granulate additionally comprises an endo-xylanase and/or a β -glucanase whereas claim 25 adds the limitation that the granulate additionally comprises starch. Claim 26 adds the limitation that the phytase is not heat

Art Unit: 1652

tolerant and claims 27-28 add the limitations that the phytase is derived from fungus or derived from *Aspergillus*. Claim 31 is directed also to the same granulate as that of claim 18.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an *Aspergillus* phytase granulate having at least 6000 FTU per gram which can be used as additive in animal feed, as taught by Nielsen et al., using a solid carrier which comprises at least 15% of an edible carbohydrate polymer, as taught by Ghani and further adding (1) an endo-xylanase and/or β -glucanase, (2) a compound which would provide at least one divalent cation, or (3) a gel-forming compound, also taught by Ghani. A person of ordinary skill in the art is motivated to make a phytase-containing granulate which also contains an edible carbohydrate and/or a divalent cation for the benefit of adding nutritional value to the granulate and also due to the fact that phytases aid in the digestion of phytate-containing substances. In addition, one of skill in the art is motivated to add a gel-forming compound for the benefit of solidifying the granules and maintaining moisture and softness. Also, one of skill in the art is motivated to add an endo-xylanase and/or β -glucanase since these are proteolytic enzymes which would help in the digestion of complex carbohydrates which might be present in the feed. One of ordinary skill in the art has a reasonable expectation of success at making the phytase-containing granulate since Ghani teaches enzyme granules which are made with solid carriers containing edible carbohydrates such as soy flour, soy grits, corn flour, ground corn cobs, corn syrup, etc., wherein said granules also contain at least one divalent cation, starch, and a gel-forming compound. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

Art Unit: 1652

13. Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995; cited in previous Office Actions) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996) as applied to claims 18-21, 24-28, and 31-35 above, and further in view of Markussen et al. (U.S. Patent No. 4106991, 1978; cited in previous Office Actions). The teachings of Nielsen et al. and Ghani have been discussed above. Neither Nielsen et al. nor Ghani teach a phytase granulate comprising a derivatized cellulose. Markussen et al. teaches enzyme granules which contain polyvinyl alcohol (PVA) and/or cellulose derivatives such as carboxy-methyl cellulose (CMC; column 3, lines 9-18). Markussen et al. does not teach phytase-containing granulates.

Claims 22-23 are drawn to the phytase-containing granulate of claim 18, as described above, further comprising PVA, derivatized cellulose or CMC.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the *Aspergillus* phytase granulate of Nielsen et al. and Ghani as described above, further comprising PVA or CMC as taught by Markussen et al. A person of ordinary skill in the art is motivated to add PVA or CMC to the phytase granulate since these are commonly used binders in the manufacture of granulates. One of ordinary skill in the art has a reasonable expectation of success at making the phytase-containing granulate further comprising PVA and/or CMC since Markussen et al. teaches enzyme granules which contain these compounds. Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made.

Art Unit: 1652

14. Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995; cited in previous Office Actions) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996) and Markussen et al. (U.S. Patent No. 4106991, 1978; cited in previous Office Actions) as applied to claims 22-23 above, and further in view of Haarasilta (GB 2-139868A, 1984). The teachings of Nielsen et al., Ghani and Markussen et al. have been discussed above. Neither Nielsen et al., Ghani or Markussen et al. teach a phytase granulate comprising an edible oil. Haarasilta teaches a fodder in granulated form which comprises soy oil (page 2, lines 13-15). Haarasilta does not teach a phytase granulate.

Claims 39 and 40 are directed to the phytase-containing granulate of claim 22 as described above, further comprising soy oil, or CMC and soy oil.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the *Aspergillus* phytase granulate of Nielsen et al., Ghani and Markussen et al. as described above, further comprising soy oil as taught by Haarasilta. A person of ordinary skill in the art is motivated to add soy oil to the phytase granulate to facilitate binding of hydrophobic compounds which may be part of the granulate, to add nutritional value to the granulate or as a lubricant to avoid adhesion in the granulator or the extruder. One of ordinary skill in the art has a reasonable expectation of success at making the phytase-containing granulate further comprising soy oil since Haarasilta teaches fodder granules which contain soy oil. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

Art Unit: 1652

15. Applicants submit that claims 18-19, 26-28, and 31, which were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Jacobsen et al. (WO 92/12645, August 6, 1992), are patentable over the prior art of record since neither Nielsen et al. nor Jacobsen et al. teach a carrier which is non-fibrous. In addition, Applicants argue that the Examiner has not presented a prima facie case of obviousness when combining the teachings of these references. Therefore, Applicants request the withdrawal of the obviousness rejection.

Applicants also submit that claims 19, 21, 22, 25 and 39, which were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Rokey et al. (U.S. Patent No. 5480673, 1996), are patentable over the prior art of record since Rokey et al. teaches a final product which is cooked. Applicants assert that combining the teachings of Nielsen et al. and Rokey et al. would render an inactive phytase granulate since, according to Applicants, Rodriguez et al. (Biochem. Biophys. Res. Comm. 268:373-378, 2000) teaches that phytases are generally not thermostable. Therefore, it is Applicant's opinion that a phytase which is exposed to a maximum cooking temperature of up to 300 F, would have negligible activity. In view of this, Applicants request the withdrawal of the obviousness rejection.

16. The Examiner acknowledges Applicant's arguments in regard to a carrier which is non-fibrous and the teachings of Rodriguez et al. in regard to the thermostability of phytases, however these arguments have been rendered moot in view of the new rejections being applied in the instant Office Action.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 18-23, 31-35, 39-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-16, 22 of U.S. Patent No. 6500426. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 7-11, 13-16, and 22 of U.S. Patent No. 6500426 are directed to an enzyme granulate, or composition thereof, suitable for animal feed wherein the granulate is made by mixing water and the enzyme with a solid carrier comprising at least 15% (w/w) of an edible carbohydrate polymer, or to an enzyme granulate as described further comprising at least one divalent cation, a gel-forming compound, a cellulose derivative

Art Unit: 1652

such as CMC, PVA, or an edible oil such as soy or canola oil. Claim 12 of U.S. Patent No. 6500426 is directed to a phytase granulate suitable for animal feed wherein the granulate is made by mixing water and the enzyme with a solid carrier comprising at least 15% (w/w) of an edible carbohydrate polymer. Claims 18-19, 31, 34 of the instant application are drawn to a phytase-containing granulate which is made with a solid carrier comprising at least 15% (w/w) of an edible carbohydrate polymer and an aqueous solution containing the phytase. Claims 20 and 21 add the limitation that the granulate should further comprise at least one divalent cation or a gel-forming compound. Claims 22-23, 39-40 add the limitation that the granulate should further comprise a derivatized cellulose such as CMC, PVA or an edible oil such as soy or canola oil. While claims 7-11, 13-16 and 22 of U.S. Patent No. 6500426 are directed to any enzyme, it is noted that the specification of U.S. Patent No. 6500426 discloses the use of phytase as one of the preferred embodiments (Abstract) in regard to the enzyme used in the granulate. As such, a phytase granulate of claims 18-23, 31-35, 39-40 of the instant application is an obvious variant of the granulate of claims 7-16, 22 of U.S. Patent No. 6500426.

Conclusion

19. No claim is in condition for allowance.
20. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.
21. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with

Art Unit: 1652

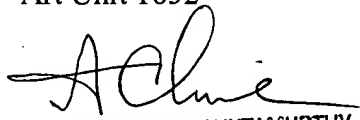
the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DR
February 19, 2003

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652


PONNATHAPUACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
RECEIVED FEB 19 2003